

1 AMY K. FISHER
2 Amy.Fisher@icemiller.com
3 BONNIE L. GALLIVAN
4 Bonnie.Gallivan@icemiller.com
5 KATHERINE A. WINCHESTER
6 Katherine.Winchester@icemiller.com
7 AUDRA J. FERGUSON-ALLEN
8 Audra.Ferguson-Allen@icemiller.com
9 ICE MILLER LLP
10 One American Square, Suite 2900
11 Indianapolis, IN 46281-0200
12 Telephone: 317-236-2100
13 Facsimile: 317-236-2219

14 Attorneys for Defendants
15 ASTRAZENECA PHARMACEUTICALS LP,
16 ASTRAZENECA LP, and MCKESSON
17 CORPORATION

18 [Additional counsel listed below]

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

In Re: NEXIUM
(ESOMEPRAZOLE) PRODUCTS
LIABILITY LITIGATION

This document relates to:

ALL CASES

Case No.: 12-md-2404 DSF (SSx)

**DEFENDANTS' REPLY IN
FURTHER SUPPORT OF MOTION
TO EXCLUDE PLAINTIFFS'
GENERAL CAUSATION EXPERT
B. SONNY BAL, M.D., J.D., M.B.A.**

Judge: Hon. Dale S. Fischer
Courtroom: 840 - Roybal

DEFENDANTS' REPLY IN FURTHER SUPPORT OF MOTION TO
EXCLUDE PLAINTIFFS' GENERAL CAUSATION EXPERT B. SONNY
BAL, M.D., J.D., M.B.A.

Case No. 12-md-2404 DSF (SSx)

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1 *randomized, crossover, controlled clinical trial, J. BONE MINER. RES.*
2 2010; 25 (10): 2205-116

3 **EXHIBITS**

4 Exhibit A: Excerpts from Transcript, Feb. 19, 2014 *Nexium®* Dep. Dr. Bal

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DEFENDANTS' REPLY IN FURTHER SUPPORT OF MOTION TO
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BAL, M.D., J.D., M.B.A.
Case No. 12-md-2404 DSF (SSx)

I. INTRODUCTION

2 The central argument in Plaintiffs' Memorandum of Points and Authorities
3 in Opposition to Defendants' Motion to Exclude Plaintiffs' General Causation
4 Expert B. Sonny Bal, M.D., J.D., M.B.A. (Master Dkt. 287) (hereinafter
5 "Response") is that their expert Dr. Bal's opinions may be shaky and not peer
6 reviewed, but the proper recourse for this Court is to allow the jury to decide what
7 weight to give his testimony, rather than exclude it altogether. *Daubert* and the
8 cases interpreting it, including the Ninth Circuit's recent *en banc* opinion in *Estate*
9 *of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463-64 (9th Cir. 2014), make clear
10 that the district court is obligated to evaluate and exclude unreliable, irrelevant
11 expert testimony through its gatekeeping function.

12 A trial court's "gatekeeping" obligation to admit only expert
13 testimony that is both reliable and relevant is especially important
14 "considering the aura of authority experts often exude, which can lead
juries to give more weight to their testimony."

15 *Stanley v. Novartis Pharm. Corp.*, No. 11-cv-03191, 2014 WL 1316217, *3 (C.D.
16 Cal. Apr. 2, 2014) (quoting *Mukhtar v. Cal. State Univ.*, 299 F.3d 1053, 1063-64
17 (9th Cir. 2002)). It is improper to simply turn such unreliable evidence over to the
18 jury to weigh.

19 Accordingly, the Court should answer all three questions presented in
20 Section III of Defendants' opening brief in the negative:

21 1. Dr. Bal is unqualified to opine that Nexium® can cause
22 osteoporosis, osteopenia and osteoporotic fractures (collectively
"OP")¹;

25 | 1 Plaintiffs assert as a fact that several studies have been published which link PPI use
26 | and OP. (Resp. at pp. 2-3; nn.2-4; pp. 13-14.) As discussed in Defendants' Motion to
Strike filed contemporaneously herewith (Master Dkt. 312), Plaintiffs' reference to

2. Dr. Bal's opinion that Nexium® is merely " associated" with OP is not "helpful" when the issue is causation; and,
3. Dr. Bal's opinion is not reliable because it is litigation-driven and there is too great an analytical gap between the data he relies upon and his conclusions.

II. ARGUMENT

A. Plaintiffs' Response Does Not Demonstrate That Dr. Bal Is Qualified To Opine About Whether Nexium Can Cause OP.

Dr. Bal² is an orthopedic surgeon who specializes in the repair and replacement of cartilage, not bone. **Exh. A** (Bal Dep. 7:6-13.) To the extent that he deals with bones, his practice consists of surgically repairing them. (*Id.* at 108:10-15.) While AstraZeneca does not dispute that he may have “exceptional familiarity and expertise with . . . bone,” this expertise has nothing to do with calcium absorption in the gastrointestinal tract or whether treatment with Nexium can inhibit this absorption so as to lead to reduced bone mineral density and OP. Dr. Bal professes no particular expertise in this core issue. Noticeably absent in Plaintiffs' Response regarding his qualifications (Resp. at p. 4, l. 20 – p. 5, l. 6, p. 8, ll. 12-15), are citations to Dr. Bal's own testimony or his CV. That comes as no surprise; Dr. Bal testified that: “When people come to us with a broken leg, they

studies their expert never reviewed or relied upon is improper. Regardless, these studies do not establish causation as a "fact." Defendants' expert authored one of the studies and opines that there is insufficient evidence to conclude that PPIs play a causal role in OP. (Master Dkt. 255-4, Targownik Rpt., p. 9.)

² The cited portions of Dr. Bal's February 19, 2014 deposition transcript in this matter ("Bal Dep.") are attached as **Exhibit A** to the Declaration of Katherine A. Winchester in Support of Defendants' Reply in Further Support of Motion to Exclude Plaintiffs' General Causation Expert B. Sonny Bal, M.D., J.D., M.B.A.

1 come to us not to review literature but to fix the broken leg." **Exh. A** (Bal Dep.
 2 108:13-15.)

3 Plaintiffs sole support for Dr. Bal's qualifications is that (1) he is an
 4 orthopedic surgeon who has operated on patients some of whom have OP and (2)
 5 he has read some medical literature discussing the relationship between PPI's and
 6 OP. On this basis alone, they assert that he is "exceptionally" qualified to testify as
 7 to whether treatment with Nexium can cause OP. They also argue that Dr. Bal's
 8 simultaneous involvement in the *Fosamax* litigation in which he expressed
 9 scientific positions that contradict his core opinion in this case should not taint his
 10 qualifications here. Neither argument should persuade this Court to find Dr. Bal
 11 qualified on the issue at hand – whether **Nexium®** can **cause** OP.

12 Moreover, the fact – standing alone – that Dr. Bal is a medical doctor does
 13 not qualify him to testify here. As discussed in Defendants' opening brief, the
 14 question is whether the testimony falls within the expert's area of **relevant**
 15 **experience**. (See Master Dkt. 255, p. 13 and cases cited therein.) Because Dr. Bal
 16 is not opining on surgical technique or even whether surgery is needed, he is not
 17 qualified because his experience is not relevant. Dr. Bal bases his opinion on his
 18 reading of epidemiologic scientific literature and their posited mechanisms of
 19 action relating to calcium homeostasis. His clinical work as a surgeon does not
 20 lend any particular expertise to reliably undertake this expert analysis and reach a
 21 relevant, reliable opinion based upon them. *Mascarenas v. Miles, Inc.*, 986 F.
 22 Supp. 582, 593 (W.D. Mo. 1997) (cancer surgeon not an expert in cancer
 23 causation).

24 Plaintiffs' cited cases do not provide to the contrary. First, neither *Stanley*
 25 nor *Tucker* address the issue. In *Stanley*, the plaintiff was a cancer patient who
 26 claimed that her osteonecrosis was caused by bisphosphonate use. 2014 WL

1 1316217 at *8. Her expert dentist was a specialist in osteonecrosis in cancer
 2 patients, had published on osteonecrosis caused by bisphosphonates and had
 3 reviewed all of her medical and dental records and the depositions of all of the
 4 treating physicians. *Id.* In *Tucker v. SmithKline Beecham Corp.*, the doctor
 5 expert's credentials were "undisputed." 701 F. Supp. 2d 1040, 1047 (S.D. Ind.
 6 2010). Regardless, the expert psychiatrist, who testified about whether treatment
 7 with an anti-depressant can increase the risk of suicide, was also a
 8 neuropsychopharmacologist (specialist in how the brain reacts to medicine) and he
 9 had "written many peer-reviewed medical journal articles concerning the SSRI
 10 class of drugs, including [the drug at issue], and the risks and benefits of those
 11 drugs." *Id.* Dr. Bal, having never studied or published on PPIs generally or
 12 Nexium® specifically, is not in the same position. And, he professes no specialty
 13 in how medicine impacts any part of the body.

14 Finally, *In re Avandia*, is distinguishable for two reasons. First, the court
 15 noted that the movant "did not elaborate on the challenge" that as a cardiologist the
 16 expert was not particularly qualified to analyze and draw conclusions from
 17 epidemiologic research. No. 07-md-01871, 2011 WL 13576, *10 (E.D. Pa. Jan. 4,
 18 2011). Second, the court recognized that the doctor was a professor and researcher
 19 specializing in "lipoprotein metabolism" including "apoB as a marker for vascular
 20 disease" – the precise issue in the litigation. *Id.* The same does not hold true here.

21 Next, Plaintiffs argue that it would be "prejudicial" to hold Dr. Bal's very
 22 recent testimony in the *Fosamax* litigation against him. (Resp. at p. 10, l. 28.) The
 23 *Fosamax* deposition took place 1 month **before** his deposition here and less than
 24 two months **after** he submitted his Rule 26(A) Report in this case. As such, his
 25 testimony in *Fosamax* came during the height of his duties in this litigation. When
 26 deposed in *Fosamax*, (at best) he forgot the opinions expressed in his *Nexium*

1 expert report. When deposed in *Nexium*, Dr. Bal could recall little about his prior
 2 testimony. Notably, the deposition testimony AstraZeneca cites here, was not
 3 focused on "a particular Fosamax plaintiff" or other case-specific details. The
 4 testimony instead involved the **science** underlying his fracture opinion in *Fosamax*
 5 as it relates to the science underlying his opinion here. Dr. Bal was unable or
 6 unwilling to discuss those issues.

7 It is axiomatic that one cannot be deemed an "expert" if his recall of the
 8 relevant subject matter is that limited. In *Fosamax*, he was defending a
 9 pharmaceutical manufacturer. Here he is on the other side. Accordingly, Dr. Bal's
 10 inability to recall core concepts from one month to the next shows either that the
 11 issues discussed in the deposition are not those he addresses in his ordinary clinical
 12 practice or his testimony is influenced by litigation. Either results in his exclusion.

13 Moreover, Dr. Bal alleges that *Nexium*® "may exert a direct action on
 14 skeletal cells called osteoclasts . . . leading to altered bone turnover." (Resp. at p.
 15 15, ll. 1-4.) This is precisely how bisphosphonates like *Fosamax*® work.
 16 Bisphosphonates slow or stop osteoclasts from resorbing bone and releasing
 17 calcium. (See, e.g., *id.* at pp. 9-10.) In *Fosamax*, Dr. Bal says a direct action on
 18 osteoclasts cannot cause fracture. Here he says it does.

19 **B. Plaintiffs' Response Highlights The Lack of Known Mechanism of
 20 Action.**

21 Dr. Bal has not identified **any** scientific basis for his opinion that *Nexium*®
 22 **use** "leads to poor calcium intake." (*Id.* at p. 9.) Yet, he opines that this is the
 23 plausible mechanism by which *Nexium*® causes the types of injuries alleged by
 24 Plaintiffs here. In fact, he never even tried to research the proposition. **Exh. A**
 25 (Bal Dep. 133:5-9.)

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1 If he had, he might have located (as Defendants' experts did) the
 2 independent clinical studies *Hansen 2010*³ and *Wright 2010*⁴ which both found
 3 that acid suppressors (including Nexium®) do not reduce calcium absorption.
 4 (Master Dkt. 255-4, Targownik Rpt. at p. 7) ("multiple recent studies evaluating
 5 calcium absorption [and PPI use] have not shown any deleterious effect on calcium
 6 absorption, except when evaluating solely the absorption of calcium carbonate in
 7 the non-fed state."); (Master Dkt. 256-5, Bikle Rpt. at p. 16) ("inhibiting calcium
 8 absorption by blocking gastric acid secretion and thus reducing the solubilization
 9 of calcium salts, has not been shown to reduce intestinal calcium absorption when
 10 put to the test in humans").⁵ Dr. Bal was unfamiliar with these studies. **Exh. A**
 11 (Bal Dep. 139:2-14.) Rather, he admitted at his deposition that *Ensrud*⁶ (the only
 12 calcium absorption study he reviewed) did not study acid suppressing medication
 13 at all. (*Id.* at 136:1-11.) Rather, it simply found that women with low calcium
 14 intake and absorption rates have more hip fractures. (*Id.*) It did not study **why**
 15 those women had low calcium absorption. (*Id.*)

16 _____
 17 ³ Hansen K.E., et al., *Do Proton Pump Inhibitors decrease calcium absorption?*, J. BONE
 18 MINER. RES. 2010; 25 (12): 2510-19.

19 ⁴ Wright M.J., et al., *Inhibiting gastric acid production does not affect intestinal calcium*
 20 *absorption in young, healthy individuals: a randomized, crossover, controlled clinical*
trial, J. BONE MINER. RES. 2010; 25 (10): 2205-11.

21 ⁵ Plaintiffs confuse two concepts. (Resp. at p. 19.) It is accepted that decreased calcium
 22 uptake can lead to osteoporosis. That is not at issue here. **What is** at issue is whether
 23 Nexium® can decrease calcium uptake. Plaintiffs assert incorrectly that "Defendants'
 24 experts offer no opinion or evidence to refute that Nexium® or any other PPI can cause a
 25 decrease in calcium uptake." (*Id.*) As discussed herein, Defendants' experts' reports
 26 disclose and discuss *Wright* and *Hansen* both which disprove the proposition that
 27 Nexium® causes decreased calcium uptake (which then could cause osteoporosis).

28 ⁶ Ensrud K.E., *Low Fractional Calcium Absorption Increases the Risk for Hip Fracture*
 29 *in Women with Low Calcium Intake*, ANNALS INT'L MED. 2000; 132 (5): 345-53.

1 Regardless, as discussed above, Dr. Bal's opinion that Nexium® reduces
 2 calcium intake – is not his only speculated method by which he believes Nexium®
 3 use may be "causally associated" with OP. Rather, Dr. Bal **also** states that
 4 Nexium® (like Fosamax®) has a direct effect on osteoclasts which, if true, would
 5 protect bone by preserving calcium in bone. Thus, his opinion that reduced bone
 6 turnover from Nexium® use is bad for bone is antithetical to his *Fosamax* opinion.

7 **C. Plaintiffs' Response Confirms That Dr. Bal Is Testifying As To An**
 8 **"Association" Only. As Such, His Testimony Is Unhelpful.**

9 Plaintiffs affirm that Dr. Bal's opinion is that Nexium® is "causally
 10 associated" with OP – not that Nexium® **causes** OP. (Resp. at pp. 1, 12.) This is
 11 consistent with his expert report and his necessary concession that his report
 12 contained a full and complete statement of all of his opinions in this case.
 13 Accordingly, his "association"-only opinion is "unhelpful."

14 Plaintiffs do not argue against the established proposition that "association"
 15 does not equal causation. (Master Dkt. 255, p. 17; *see also generally* Resp.) In
 16 fact, *In re TMI Litig.*, cited by Plaintiffs, reiterates that "Association is a term of art
 17 in epidemiology. It is defined as '[t]he degree of statistical dependence between
 18 two or more events or variables. . . Association does not necessarily imply a causal
 19 relationship.'" 193 F.3d 613, 710 n.159 (3d Cir. 1999). Rather, they argue that
 20 causation may be "impl[ied]" from association studies and that such studies "add[]
 21 weight." (Resp. at p. 13, lines 11, 15.) However, they admit that no inference can
 22 be drawn from associational studies alone. Rather, association studies must be
 23 "[c]ombined with accepted mechanisms of action, and corroborating evidence from
 24 other scientific studies, when combined with other supportive data." (*Id.*)⁷ And,

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7 Plaintiffs assert that Defendants' experts require "black and white," "gold standard"

1 Plaintiffs do not have any such corroborating evidence. Plaintiffs do not offer
 2 "accepted" mechanisms of action supported by any studies. **Exh. A** (Bal Dep.
 3 118:24-119:5.) They rely upon no other clinical studies or supportive data.
 4 Accordingly, Dr. Bal's association-only opinion is not "helpful" to the only issue
 5 presented here – whether Nexium® can cause OP.

6 Plaintiffs' Response highlights this dichotomy between evidence of
 7 association versus causation when it discusses a study conducted by Targownik in
 8 2008. (Resp. at p. 3.) Plaintiffs assert that this association study establishes that
 9 Nexium® use increases the risk of hip fracture. **Dr. Targownik submitted an**
 10 **expert report in this case that undermines Plaintiffs' lay interpretation of her**
 11 **work.**⁸ She conducted the study, and she does not believe that the scientific
 12 evidence (including her multiple studies) supports that Nexium® use causes OP -
 13 even though her 2008 study found an **association** between the two events. (Master
 14 Dkt. 255-4, Targownik Rpt.) As Dr. Targownik explains: receiving the morning
 15 newspaper is highly associated with the sun rising. However, the newspaper
 16 delivery does not cause the sun to rise nor the converse. (*Id.* at p. 3.) An
 17 association is "nothing more than a temporal association between variables." **Exh.**
 18 **A** (Bal Dep. 30:23-25.) "When you see an association, you cannot or should not
 19 jump to a cause and effect relationship. That requires more data." (*Id.* at 32:8-12.)

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 23 evidence before causation can be inferred. (Resp. at p. 16.) However, their cites to Dr.
 24 Bal do not support this assertion. Moreover, Dr. Targownik's report explains that criteria
 25 are employed by epidemiologists "to determine whether an observational association is
 26 likely to represent causation . . ." (Master Dkt. 255-4, Targownik Rpt., p. 4.)

27 8 Plaintiffs' attorneys in the Response, not their purported expert Dr. Bal, make this
 28 assertion about Dr. Targownik's work. It is unquestionably an inadmissible lay opinion.

D. Plaintiffs' Response Fails To Address The Fundamental Underlying Analytical Gaps Which Render Dr. Bal's Opinion Unreliable.

None of the arguments set forth in Plaintiffs' Response demonstrate that Dr. Bal's opinion in this case should be deemed reliable under Rule 702 and *Daubert*.⁹ To the contrary, there is too large of an analytical gap between the items he relies upon and the opinion he reaches.¹⁰ In sum, the association studies he relies upon:

- do not agree that causation has been established,¹¹
- are not on Nexium® – the only medication Dr. Bal implicates in his opinions, and
- at best speculate with regard to possible mechanisms of action.

Dr. Bal's opinion cannot reliably extend to a conclusion where the literature upon which he relies has not reached such a conclusion and he has done no independent research. Law is meant to lag science, not allow speculation to stand as science.

First, Plaintiffs assert that Dr. Bal should be able to rely upon studies that never studied Nexium®, or studied it only as part of a class of medications. (Resp. at pp. 11-12.) Whether or not it would be scientifically appropriate,¹² Dr. Bal has

⁹ As proffered "scientific" evidence, Dr. Bal's opinion is subject to the *Daubert* factors as discussed in Defendants' opening brief. *Cf. United States v. Hankey*, 203 F.3d 1160, 1168 (9th Cir. 2000) (courts have "broad discretion" in reviewing proffered nonscientific, *i.e.*, *Kumho* expert evidence).

10 Additionally, as discussed in the opening brief, Dr. Bal's opinion is driven by litigation. (Master Dkt. 255, pp. 18-19.) Plaintiffs do not address this argument. In the interest of brevity, Defendants therefore incorporate by reference their prior brief as it relates to this issue.

11 Plaintiffs in their Response do not contest this point.

12 Plaintiffs argue that because the FDA issued classwide PPI labeling for bone fracture, it would be reliable for Dr. Bal to rely on studies conducted on other PPIs. Setting aside that Dr. Bal precludes this methodology by contending there is no class-wide effect, the

1 decided that his opinion is not generalizable to other PPIs and, thus, he **only** opines
 2 that Nexium® is causally associated with OP. **Exh. A** (Bal Dep. 78:11-14, 121:23-
 3 122:25.) Relying on studies of other medications, therefore, admittedly is not
 4 supportive or reliable because it would be inconsistent with his opinion that it is
 5 not a class-wide effect. *Cf. Tucker*, 701 F. Supp. 2d at 1056 (allowing expert to
 6 rely upon studies of a class of medications, but no contention that expert himself
 7 did not know the medications to be sufficiently similar to treat as a class).

8 Next, Plaintiffs contend that because Dr. Bal necessarily limited his opinions
 9 to only certain fracture sites, it therefore must be reliable. (Resp. at p. 16.)
 10 Plaintiffs provide no support for the point that a narrow rather than broad opinion
 11 is necessarily more reliable. Regardless, Dr. Bal's posited opinion is that Nexium®
 12 causes osteoporosis and only "osteoporotic" fractures. However, the studies he
 13 relies upon did not find that PPIs were associated with a reduction in bone mineral
 14 density (BMD), *i.e.*, osteoporosis. **Exh. A** (Bal Dep. 148:15-149:9.)

15 Further, Plaintiffs contend that Dr. Bal implicitly applied the Bradford Hill
 16 criteria and therefore his opinion is more reliable. (Resp. at p. 17.) Nothing in Dr.
 17 Bal's report or deposition discloses that Dr. Bal used this or any other recognized
 18 methodology to assist in determining whether an observed association is causal.
 19 Rather, Plaintiffs in their Response **argue** that what they read about Dr. Bal's
 20 opinions seem to comport with Plaintiffs' interpretation of this epidemiologic

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 22 FDA label and communications regarding the label are not, in themselves, any evidence
 23 of causation. Federal regulations make clear that a "causal relationship need not have
 24 been proved" for a warning to issue. 21 C.F.R. § 201.57(e). Furthermore, the FDA
 25 language at issue does not assert or imply an established causation ("The available data . . .
 26 suggest a **possible** increased risk of fractures of the hip, wrist, and spine. . . . [T]here is
 uncertainty about the magnitude of this risk."). (Master Dkt. 288-3, Exh. J.) (emphasis
 added).

1 criteria. Regardless of whether Dr. Bal would be competent to apply the criteria
 2 (which Defendants deny), Plaintiffs and their counsel undoubtedly are not.
 3 Moreover, the cites to Dr. Bal's deposition transcript do not relate to the Bradford
 4 Hill criteria that Plaintiffs cite: temporality, strength of association, alternative
 5 explanations, consistency or biologic plausibility. (See Resp., p. 17, cited Bal
 6 Dep.)¹³ The only disclosed expert to engage in this analysis was the
 7 gastroepidemiologist Dr. Targownik. (Master Dkt. 255-4, Targownik Rpt., pp. 4-
 8 9.) She was explicit in use of the methodology and concluded that application of
 9 the criteria did not imply a causal relationship. (*Id.* at p. 9.)

10 Finally, Plaintiffs argue that lack of an "established" mechanism of action
 11 and the presence of Defendants' own experts cannot *ipso facto* make their expert
 12 inadmissible. Plaintiffs misunderstand the significance of these issues. As to the
 13 lack of accepted mechanism of action, such missing evidence is "significant" if not
 14 dispositive to a *Daubert* analysis as to whether the expert's opinion is reliable.
 15 *Schudel v. Gen. Elec. Co.*, 120 F.3d 991, 997 (9th Cir. 1997). Additionally, as
 16 addressed above, Plaintiffs contend that causation may be "implied" from the items
 17 Dr. Bal relies upon which include his opinions regarding a "plausible", but not
 18 "established," mechanism of action. However, *Tucker, supra*, does not support
 19 reliance upon a merely "plausible" mechanism of action. Rather, the mechanism
 20 must be "accepted," a difference that Dr. Bal appears to understand. **Exh. A** (Bal
 21 Dep. 106:25-107:10) (stating that he did not recall "any accepted or recognized")

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 24 13 For example, Bal Dep. 73:8-13 (which was cited for alternative explanations,
 25 consistency with scientific knowledge and biologic plausibility) states nothing more than
 26 how Nexium® works: Q. Do you know the clinical pharmacology is by which proton
 pump inhibitors work? A. Yeah. They decrease the secretion of acids and quite
 dramatically in the stomach. **Exh. A** (Bal Dep. 73:8-13.)

1 mechanism by which Fosamax® could cause fractures.)

2 Additionally, Defendants' expert reports are not offered, as Plaintiffs'
 3 contend, as direct evidence that Plaintiffs' expert is inadmissible.¹⁴ Rather, they
 4 are offered to demonstrate, based on good science, that there is no causal
 5 connection between treatment with Nexium and loss of bone density leading to
 6 possible fractures. Plaintiffs' fear that their purpose is instead to attack Dr. Bal's
 7 opinions merely highlights that his opinions cannot withstand any measure of valid
 8 scientific scrutiny. Finally, Defendants' expert reports address gaps in Dr. Bal's
 9 analysis regarding, *inter alia* whether calcium absorption has ever been studied in
 10 PPI users – given that Dr. Bal declined to undertake that research despite it being
 11 central to his opinions and made available to him through Defendants' expert
 12 reports. **Exh. A** (Bal Dep. 138:14-139:14.)

13 III. CONCLUSION

14 FED. R. EVID. 702 and *Daubert* demand scrutiny of experts. The old refrain
 15 of allowing the jury to sort it out has ended. An admissible expert must be
 16 qualified and his testimony must be relevant and reliable. Dr. Bal does not meet
 17 any of these requirements and his testimony must be excluded.

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24 ¹⁴ Plaintiffs cite *Hangarter v. Provident Life and Acc. Ins. Co.* for the point that
 25 competing expert opinions go to the weight, rather than the admissibility of evidence.
 26 (Resp. at p. 18 n.14.) However, *Hangarter* does not address the issue, but rather whether
 an expert's selection of documents is a *Daubert* issue. 373 F.3d 998, n.14 (9th Cir. 2004).

1 DATED: May 22, 2014

ICE MILLER LLP

3 By: /s/ Katherine A. Winchester
4 AMY K. FISHER
5 BONNIE L. GALLIVAN
6 KATHERINE A. WINCHESTER
7 AUDRA J. FERGUSON-ALLEN

8 JAMES FREEBERY
9 jfreebery@mccarter.com
10 MAKENZIE WINDFELDER
11 mwindfelder@mccarter.com
12 McCarter & English
13 Renaissance Centre
14 405 N. King Street, 8th Floor
15 Wilmington, DE 19801
16 Telephone: 302-984-6300

17 PETER A. STROTZ, BAR NO. 129904
18 pstrotz@kslaw.com
19 WILLIAM E. STEIMLE, BAR NO. 203426
20 wsteimle@kslaw.com
21 MEGAN R. NISHIKAWA, BAR NO. 271670
22 mnishikawa@kslaw.com
23 King & Spalding LLP
24 101 Second Street
25 Suite 2300
26 San Francisco, CA 94105
27 Telephone: +1 415 318 1200
28 Facsimile: +1 415 318 1300

29
30 Attorneys for Defendants ASTRAZENECA
31 PHARMACEUTICALS LP, ASTRAZENECA
32 LP, and MCKESSON CORPORATION

CERTIFICATE OF SERVICE

I, Katherine A. Winchester, declare:

I am a citizen of the United States and employed in Indianapolis, Indiana. I am over the age of eighteen years and not a party to the within-entitled action. My business address is One American Square, Suite 2900, Indianapolis, Indiana 46282.

On May 22, 2014, I served a copy of the within document(s):

**DEFENDANTS' REPLY IN FURTHER SUPPORT OF MOTION TO
EXCLUDE PLAINTIFFS' GENERAL CAUSATION EXPERT
B. SONNY BAL, M.D., J.D., M.B.A.**

12 On all parties in this action by causing a true copy thereof to be distributed as
13 follows:

BY ELECTRONIC SERVICE VIA PACER: I caused such documents to be transmitted via electronic mail to the stated parties via an electronic service known as PACER.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on May 22, 2014, at Indianapolis, Indiana.

/s/ Katherine A. Winchester
KATHERINE A. WINCHESTER

14

DEFENDANTS' REPLY IN FURTHER SUPPORT OF MOTION TO
EXCLUDE PLAINTIFFS' GENERAL CAUSATION EXPERT B. SONNY
BAL, M.D., J.D., M.B.A.
Case No. 12-mc-2404 DSF (SSx)